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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/543,001

05/23/2006

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UTSJ:041US/10507807

1190

32425 7590 02/17/2010  
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EXAMINER

BRUTUS, JOEL F

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

02/17/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/543,001	<b>Applicant(s)</b> SARDAR ET AL.	
	<b>Examiner</b> JOEL F. BRUTUS	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21,23-35,37,39 and 42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21,23-35,37,39 and 42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/4/10 has been entered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-5, 9-13, 17-18, and 23-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Dreher et al (US Pat: 5,303,709).and Van de Velde (US Pat: 5,568,208) is not relied on for the rejection but as a proof of the teaching of backscattered light)

Regarding claims 1, 3-4, 11-12, 29, 31-33 and 25-27, Dreher et al disclose system and method to diagnose diseases of the eye that anticipates the claimed invention. Dreher et al FIGS. 1a and 1 illustrates the eye 11, in which the cornea 10 serves as the foremost, transparent portion of the eye, behind which is the iris 12 and

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the lens 14. The interior of the eye 11 is of course filled with vitreous and at the rear of the eye is what is generally termed the retina composed of the layers illustrated, in FIG. 1, including the internal limiting membrane 16, the nerve fiber layer 18, the receptor system 20, the retinal pigment epithelium 22, and the choroid 23 [see column 3 lines 47-54]. Fig 1 shows light beams go through the retina and backscattered and fig 7 also shows light beams 50 go through the entire eye 11 and backscattered to the direction where they came from (emphasis added).

Dreher et al disclose a polarization technique that has the ability to diagnose the interior eye, especially early diagnosis of glaucoma [see column 8 lines 60-63]; a detector that measures absolute intensity of returned diagnostic beam [see column 7 lines 65-67, column 8 lines 1-5] and fig 2 shows two different light beams (32 and 45) that can be referred to as first and second beams (emphasis added). As disclosed herein, the detector detects absolute intensity which means maximum intensity and thereby can detect the maximum of either one of the beams (emphasis added). Dreher et al further teach a variable retarder to adjust to maximize the intensity of the light in the polarized state [see column 5 lines 50-53].

Dreher et al teach a polarization sensitive detection means [see column 2 lines 60-64]; measuring polarization shift [see column 4 lines 33- 40]. Dreher et al also teaches an ellipsometer to capture and analyze polarization information [see column 6 lines 6-9]; incident diagnostic beam could be scanned by a scanning unit [see column 6 lines 65- 68]; choroid (or choroidal tissue) [see column 3 lines 55-56].

With regards to Neovascularization, Applicant discloses that neovascularized tissues may be ant limited to diabetic retinal tissue, choroidal capillaries and tumor tissue [see 0026, specification]. Applicant also refers to neovascularized eyes as diseased eyes [see 0056, specification]. Dreher et al teach diagnosis of certain diseases, principal among which is glaucoma [see column 3 lines 54-60].

As a proof Van de Velde teaches backscattered light form the eye [see fig 1 beam 18 and column 4 lines 18-20].

Regarding claims 5, 34, 28 and 13, Dreher et al teach the system uses a laser diode to provide a beam of light that is focus by a lens [see column 4 lines 40-44, and column 6 lines 30-50].

Regarding claims 2, 30, 24, 18 and 10, all other limitations are taught as set forth by the above teaching.

Dreher et al teach a non invasive diagnosis [see fig 3].

Regarding claim 9, all other limitations are taught as set forth by the above teaching.

Dreher et al further teach a detector that measures absolute intensity of returned diagnostic beam [see column 7 lines 65-67, column 8 lines 1-5] so fig 2 shows two different light beams (32 and 45) that can be referred to as first and second beams (emphasis added). As disclosed herein, the detector detects absolute intensity which

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means maximum intensity and thereby can detect the maximum of either one of the beams (emphasis added).

Regarding claims 17 and 23, all other limitations are taught as set forth by the above teaching.

Dreher et al teach a detector that measures absolute intensity of returned diagnostic beams [see column 7 lines 65-67, column 8 lines 1-5] and fig 2 shows two different light beams (32 and 45) that can be referred to as first and second beams (emphasis added). Dreher et al teach a polarization sensitive detection means [see column 2 lines 60-64]; measuring polarization shift [see column 4 lines 33- 40]. The invention measures polarization shift of the most intense light beam since Dreher et al disclose the detector detects absolute intensity (which is the most intense, emphasis added) of returned beams; therefore, the polarization sensitive detection means has to measure shifts of the most intense beam (s) (emphasis added).

Dreher et al teach a second photo detector is used to measure the total amount of reflected intensity of the return diagnostic beam at the corresponding points on the fundus. By normalizing the intensity values obtained with the first photo detector with the corresponding values of the second detector, absolute changes in the state of polarization of the return diagnostic beam are calculated [see column 8 lines 43-50 and column 8 lines 20-31] and means and method for determining thickness of the nerve fiber layer of the fundus of the eye by measuring the polarization shift of the reflected probing light

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 6-8 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dreher et al (US Pat: 5,303,709) in view of Glaser et al (US Pat: 5,767,079) or Larrick et al (US Pat: 5,670,151).

Regarding claims 6-8 and 14-16, all other limitations are taught as set forth by the above teaching.

Dreher et al don't mention diabetes retinopathy, macular degeneration and cancer.

However, However, Glaser et al teaches method for treating ophthalmic disorders like retinal disorders, choroidal tissue, macular degeneration, neovascularization, diabetic retinopathy, ocular tumor [see column 5 lines 39-43, lines 62-67, column 1 lines 33-36 and column 6 lines 1- 13].

Larrick et al teaches a form of disorder of the eye is diabetes retinopathy [see column 2 lines 13-20].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combined Dreher with Glaser et al or Larrick et al; for the purpose of providing diagnosis to evaluate the extent or spread of the disease as to prescribe the best possible treatment; thus prevent any further eye problems or blindness.

6. Claims 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dreher et al (US Pat: 5,303,709) in view of Hay et al (US Pat: 5,632,282).

Regarding claim 19, all other limitations are taught as set forth by the above teaching.

Dreher et al further teach an array of polarizers, a micro computer, a diagnostic beam, beam splitter, ADC [see fig 3]; the system uses a laser diode to provide a beam of light that is focus by a lens [see column 4 lines 40-44]; a linear polarizer, a laser, laser diagnostic beam, array of polarizers, computer that is coupled to the detectors and the analyzer [see column 6 lines 30-50].

Dreher et al don't mention a sample tissue holder.

However, Hay et al teach a device comprises a chinrest to position the eye within the area of the beam light [see column 8 lines 18-24] and stabilizing bar to stabilize the head and thus the eye [see column 8 lines 22-24].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine the Dreher et al with Hay et al by using a



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sample holder as taught by Hay et al; in order to stabilize the desired examined area thereby to precisely and accurately focus the laser beam into the eye.

7. Claims 20-21 and 35, 37, 39 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dreher et al (US Pat: 5,303,709) in view of Hay et al (US Pat: 5,632,282) as applied to claim 19 above and further in view of Trachtman (US Pat: 5,002,384).

Regarding claims 20, 35, 39 and 42, all other limitations are taught as set forth by the above combination.

Dreher et al don't mention photodiode detector and tissue sample holder.

However, Hay et al teach a device comprises a chinrest to position the eye within the area of the beam light [see column 8 lines 18-24].

However, Trachtman teaches an apparatus for monitoring and training eye position under clinical conditions, sensors means can be photodiodes [see column 16 lines 41-56]; sample holder [see column 19 lines 8-20].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine Dreher et al with Trachtman by using its photodiode; for the purpose of having the capability of converting light into either current or voltage, depending upon the mode of operation; and with Hay et al by using its tissue holder; in order to stabilize the desired examined area thereby to precisely and accurately focus the laser beam into the eye.

Regarding claims 21 and 37, all other limitations are taught as set forth by the above teaching.

Dreher et al don't teach digital meter.

However, Trachtman teaches a digital meter [see column 19 lines 25-35 and 45-55].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine Dreher et al with Trachman by using the digital meter for higher accuracy, efficacy and greater precision.

### ***Response to Arguments***

8. Applicant's arguments with respect to claims 1-22, 23-36, 37, 39 and 42 have been considered but are moot in view of the new ground(s) of rejection.

Applicant argues that Dreher et al don't teach backscattered beam and further points out that Dr Tsing states that reflected light beam is different than backscattered light beam.

Examiner disagrees because backscattering is defined as the reflection of waves or signals back to the direction they came from and it is a diffuse reflection due to scattering (emphasis added). So Dreher et al teach light reflected from the eye is similar to backscattered light (emphasis added).

In addition, Dreher et al do teach the teaching of light backscattered from eye tissue because Fig 1 shows light beams go through the retina and backscattered and fig

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7 also shows light beams 50 go through the entire eye 11 and backscattered to the direction where they came from (emphasis added).

Applicant also mentions that the light go through the entirety of the eye tissue. That limitation is not part of any claim and both figs 1 and 7 show that light beams go through the entire eye [see figs 1 and 7].

Applicant mentions that Dreher et al invention is to measure nerve thickness and not to diagnose diseases.

Examiner disagrees because Dreher et al teach their invention concerns itself primarily with the cornea, the lens, and the nerve fiber layer 18. It is this nerve fiber layer's topographical and the thickness measurements which are crucial to the diagnosis of certain diseases, principal among which is glaucoma [see column 3 lines 54-60].

### ***Conclusion***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00 PM (Off alternative Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./  
Examiner, Art Unit 3768

/Long V Le/  
Supervisory Patent Examiner, Art Unit 3768